

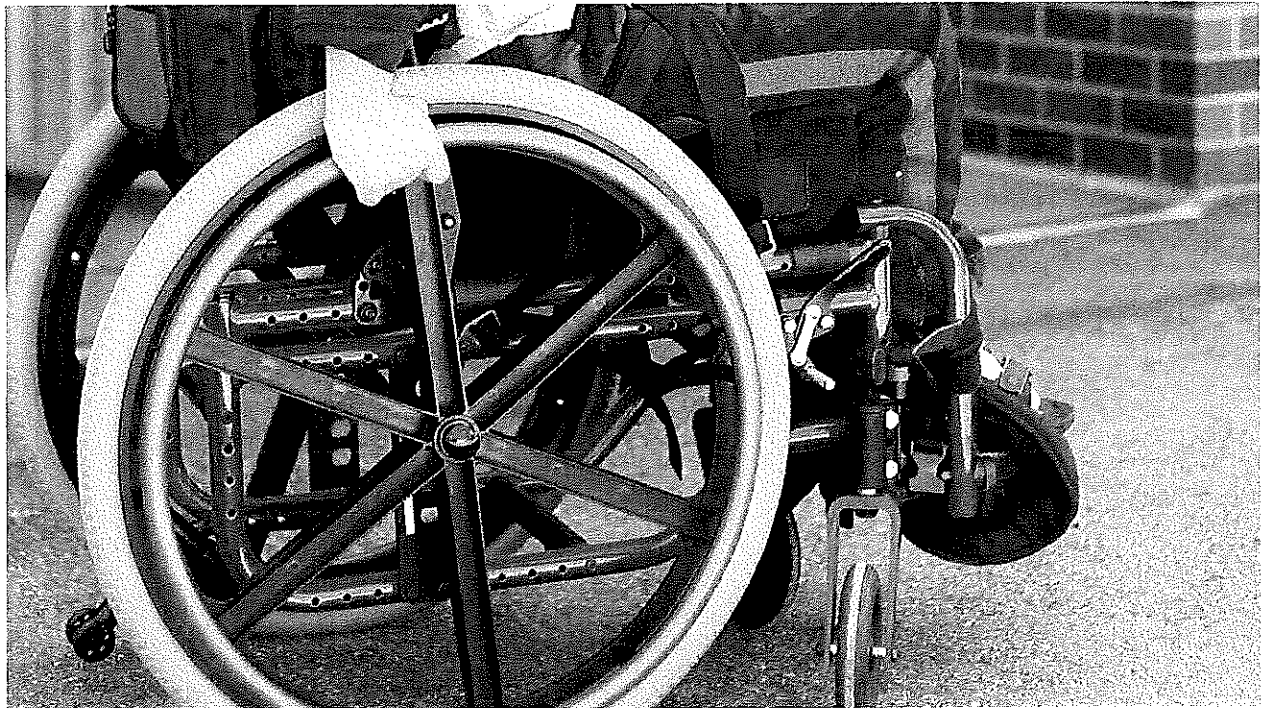
# EXHIBIT NO.

# 11

# The Mysterious Polio-Like Disease Affecting American Kids

Doctors are stumped about the condition's origins—and its treatment.

By Dan Hurley



Jaren Jai Wicklund/Shutterstock

OCTOBER 24, 2014

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COLUMBUS, Ohio—More than 100 cases of a polio-like syndrome causing full or partial paralysis of the arms or legs have been seen in children across the United States in recent months, according to doctors attending the annual meeting of the Child Neurology Society.

Symptoms have ranged from mild weakness in a single arm to complete paralysis of arms, legs, and even the muscles controlling the lungs,

leading in some cases to a need for surgery to insert a breathing tube, doctors said.

The outbreak, which appears to be larger and more widespread than what has largely been previously reported by medical and news organizations, has neurologists and the Centers for Disease Control and Prevention scrambling to find out what is causing these cases and how best to treat it.

“We don’t know how to treat it, and we don’t know how to prevent it,” said Keith Van Haren, a child neurologist at Stanford University School of Medicine. “It actually looks just like polio, but that term really freaks out the public-health people.”

When asked whether they had seen a complete recovery in any of their patients, only two of the doctors raised their hands.

**EXHIBIT NO.**

**12**

# Enterovirus Blamed for Polio-Like Acute Flaccid Myelitis in Kids

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Latest Infectious Disease News

By Peter Beholden on 10/24/2019 2:00 PM

Source: MedicineNet Health News

Researchers announced new evidence Monday that a virus is responsible for the sudden paralysis caused by polio-like acute flaccid myelitis (AFM).

The exact cause of AFM has not been determined. But in the study published in *Nature*, scientists discovered immune reactions to two types of enteroviruses in 70% of fluid samples from children with AFM. These reactions appeared in only 6% of samples from a control group of children with neurological conditions other than AFM.

Specifically, the study identified antibodies for enterovirus serotypes D68 and A71.

Enterovirus D68 (EVD68) caused a nationwide outbreak from Aug. 2014 to Jan. 2015, according to the CDC. During this outbreak, the virus sickened 1,153 people in 49 states and the District of Columbia.

Almost all the individuals infected were children who also had a history of pneumonia or wheezing, the CDC said. Health officials identified the virus in 14 patients who died during the outbreak.

## What Is Acute Flaccid Myelitis?

Acute flaccid myelitis is an extremely rare condition of the nervous system that causes the muscles and reflexes of the body to weaken, the CDC says. It may be spread to humans by mosquitoes, but people cannot spread AFM.

AFM symptoms include a sudden onset of arm or leg weakness and loss of muscle tone and reflexes, according to the CDC. Other symptoms can include facial droop, eyelid droop, difficulty moving the eyes, facial weakness, slurred speech, or problems with swallowing. The most serious potential symptom is respiratory failure.

Lab tests are required to diagnose AFM. The CDC says the rare condition occurs in less than one in a million people in the United States every year.

The agency says scientists have proposed a variety of causes of AFM, including viruses, but also environmental toxins and genetic disorders.

### **What Is Enterovirus?**

Enterovirus infections are extremely common. They belong to the family of RNA viruses, according to Charles Patrick Davis, MD, PhD. He said most people infected with enteroviruses have mild symptoms or none at all. Why some of these cases develop into AFM is unknown.

Unlike AFM itself, enterovirus infections are highly contagious, Dr. Davis said. Even if they do not develop AFM, people infected with enterovirus may nonetheless experience significant health symptoms:

- Common cold: nasal discharge, cough, mild fever, mild malaise
- Hypoxia (low oxygen in the blood): shortness of breath, wheezing, coughing, rapid breathing, skin coloration change (bluish to cherry red), rapid heart rate

- Aseptic meningitis: most common among infants and children; may also occur with a rash (on face, neck, and extremities), fever, painful headache, stiff neck, body aches, sensitivity to light, nausea and vomiting, irritability
- Serous conjunctivitis (hemorrhagic): eye pain, bleeding seen in the whites of the eyes, photophobia (avoidance of light due to discomfort)
- Myopericarditis: shortness of breath, chest pain, fever, weakness
- Herpangina: small flat sores on the oral mucosa (mouth and soft palate) that may produce blisters and ulcerate
- Pleurodynia: intermittent chest pain usually over the lower part of the rib cage; some individuals may have a plural friction rub that can be heard when the doctor examines the chest with a stethoscope
- Hand, foot, and mouth disease (HFMD): small nodules and blisters that are tender and appear gray that occur on the hands, feet, and in the oral cavity
- Encephalitis: Symptoms range from lethargy and drowsiness to personality changes, seizures, and coma.

# EXHIBIT NO.

# 13



## AFM Confirmed U.S. Cases

Language:

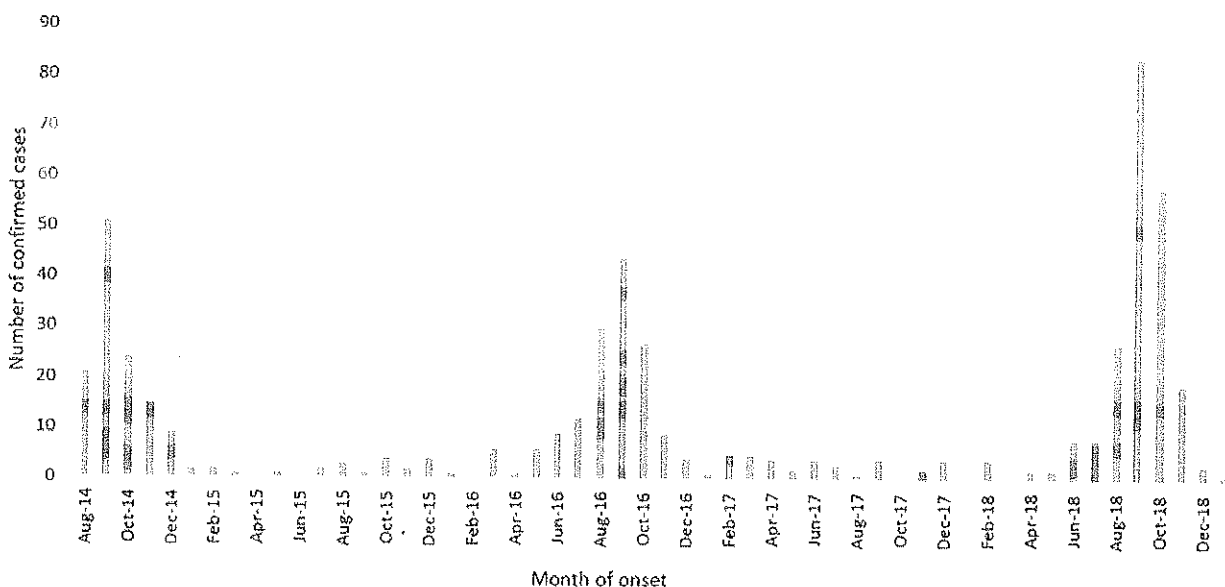
English (US)

- Español (Spanish)

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Number of confirmed U.S. AFM cases reported to CDC by month of onset,  
August 2014 - January 2019<sup>^†</sup>



<sup>^</sup> Confirmed AFM cases that CDC has been made aware of as of February 15, 2019 with onset of the condition through January 31, 2019. The case counts are subject to change.

<sup>\*</sup> The data shown from August 2014 to July 2015 are based on the AFM investigation case definition: onset of acute limb weakness on or after August 1, 2014, and a magnetic resonance image (MRI) showing a spinal cord lesion largely restricted to gray matter in a patient age  $\leq 21$  years.

<sup>†</sup> The data shown from August 2015 to present are based on the AFM case definition adopted by the Council of State and Territorial Epidemiologists (CSTE): acute onset of focal limb weakness and an MRI showing spinal cord lesion largely restricted to gray matter and spanning one or more spinal segments, regardless of age.

For more information, visit the [Case Definitions](#) page.

[Top of Page](#)

## What This Graph Shows

The graph shows the number of AFM cases confirmed by CDC as of February 15, 2019, with onset of the condition through January 31, 2019.

- So far in 2019, there have been 11 reports of PUIs, one of which has been confirmed (from North Carolina).
- In 2018, there are 215 confirmed cases of AFM. (Note: The cases occurred in 40 states across the U.S.)

Note: These 215 confirmed cases are among the total of 371 reports that CDC received of patients under investigation (PUIs). CDC received increased reports for PUIs with onset of symptoms in August, September, and October. CDC and state and local health departments are still investigating some of these PUIs.

- In 2017, CDC received information for 35 confirmed cases of AFM. (Note: The cases occurred in 16 states across the U.S.)
- In 2016, 149 people were confirmed to have AFM. (Note: The cases occurred in 39 states across the U.S. and DC)
- In 2015, 22 people were confirmed to have AFM. (Note: The cases occurred in 17 states across the U.S.)
- From August to December 2014, 120 people were confirmed to have AFM. (Note: The cases occurred in 34 states across the U.S.)
- The case counts represent only those cases for which information has been sent to and confirmed by CDC.

It is currently difficult to interpret trends of the AFM data. Collecting information about patients under investigation (PUIs) for AFM is relatively new. There may initially be more variability in the AFM data from year to year making it difficult to interpret or compare case counts between years.

We defer to the states to release additional information on cases as they choose.

[Top of Page](#)

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- Content source:
  - National Center for Immunization and Respiratory Diseases, Division of Viral Diseases

# EXHIBIT NO.

# 14

### 3rd case of polio-like disease confirmed in Massachusetts, more suspected

Posted Dec 27, 2018

#### 2018 confirmed cases of acute flaccid myelitis (AFM) by state (N=182)\*



\*Confirmed AFM cases as of December 21, 2018. Patients under investigation are still being classified, and the case counts are subject to change. Case counts will be updated every Monday.

The Centers for Disease Control and Prevention has posted a map showing as of Dec. 21 which states have confirmed cases to date this year of the polio-like disease acute flaccid myelitis. (CDC graphic)

Comment

Masslive.com

**By Anne-Gerard Flynn | Special to The Republican**

The number of confirmed cases of acute flaccid myelitis, a rare polio-like disease, has increased by one in Massachusetts while cases under investigation have increased by two.

According to the Massachusetts Department of Public Health, there are now "3 confirmed, 1 probable and 5 suspect cases of AFM in Massachusetts."

The Centers for Disease Control and Prevention weekly report on the emerging disease indicates there are currently 182 confirmed cases of AFM in 38 states as well as in New York City to date this year among a total of 336 reports that the CDC has received of patients under investigation for AFM as of Dec. 21.

States reporting their first confirmed cases as of Dec. 21 include Florida and South Dakota. States with no confirmed cases to date this year include Alaska, Connecticut, Delaware, Hawaii, Idaho, Maine, New Hampshire, Oregon, Tennessee, Utah, Vermont and West Virginia as well as the District of Columbia.

Although a rare condition, the CDC began to release weekly reports in October of patients under investigation for AFM after noting an increase starting in August as certain seasonal viruses begin to circulate.

At that time, Massachusetts had two confirmed cases and four suspected cases, with the CDC reporting 62 confirmed cases in 22 states as of Oct. 17. There is no specific clinical management for the disease that involves the expertise of both infectious disease specialists and neurologists, and it can take the CDC a few weeks to classify and confirm suspected cases sent by state health departments.

AFM is defined by the Council of State and Territorial Epidemiologists as a "rare and very serious condition that affects the nervous system causing weakness in the arms or legs and is, in some instances, also associated with long-term disability."

The disease, which is seen mainly in children, has been compared to poliomyelitis because its symptoms can include limb paralysis, though the CDC has said no confirmed cases have yet to test positive for the polio virus.

It can be diagnosed through spinal cord fluid and an MRI, but no single pathogen or specific inflammatory process has been identified yet as the cause of AFM. Evidence of a virus, the CDC has said, has been more often found in respiratory and stool samples than in spinal fluid.

The CDC has detected coxsackievirus A16, EV-A71 and EV-D68 in the spinal fluid of four of 508 confirmed cases of AFM since 2014, when it began tracking the disease. For all other patients, the CDC has said, no pathogen has been detected in their spinal fluid to confirm a cause.

The onset of AFM sometimes presents first as a respiratory condition and then progresses to muscle weakness, including facial droop or weakness. Parents are urged to contact their health care provider if they notice such symptoms.

5 questions and answers about acute flaccid myelitis, the polio-like illness confirmed in two Mass. children

The state Department of Public Health is investigating four other suspected cases of the condition.

—David Goldman / AP, File Boston.com

**By**

~~Danlynn Dwyer~~

October 19, 2018

Two children in Massachusetts have contracted a serious, rare illness that causes muscle weakness and paralysis, according to the state's Department of Public Health.

The state's first case this year of acute flaccid myelitis, or AFM, was confirmed in August, according to the department, which is investigating four other suspected cases. There is no specific treatment or cure for the illness.

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The Centers for Disease Control and Prevention has been actively investigating AFM since 2014 and “monitoring” the activity of the disease. According to the CDC, from August 2014 through September 2018, 386 confirmed cases of AFM have been reported to the federal agency, and the cause for the majority of the cases has not been confirmed. So far in 2018, 62 cases have been confirmed in 22 states.

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We spoke with Dr. Leslie Benson, assistant director of the neuro-immunology program at Boston Children's Hospital, to learn more about the illness, which has been described as being similar to polio.

**What is acute flaccid myelitis?**

It is not “totally clear” what causes AFM, Benson explained.

“Most likely it appears to be a viral infection — specifically a fairly common viral infection,” she said. “But we don't know why in some patients it may affect the

spinal cord. When it does infect the spinal column or parts of the brain stem, it can cause fairly sudden onset weakness and paralysis.”

The effects of AMF range from weakness of the facial muscles to problems with bladder control to weakened breathing.

“It’s not just one virus that can do this. There are a few viruses that can do this,” she said. “And we can’t always detect them in each individual patient for a variety of reasons.”

The vast majority of cases are in children, particularly young kids, Benson said. She said in her experience, four is the average age of the patients, though it is possible in younger children.

“I’ve seen [it in] anyone from one to two, up to teenagers,” she said.

### **What is the treatment?**

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There’s no specific treatment that helps or reverses the effects of the condition.

“The main part of treatment is supportive,” Benson said. “If they can’t breathe, we put them on a ventilator. If they are having pain, we treat their pain. We give them a lot of physical therapy, and they get a lot of rehabilitation.”

While patients can show gradual improvement, she said that many are left with permanent long-term weakness.

### **Why is it being described as polio-like?**

Benson said the polio virus is not the culprit in the AFM cases.

“[AFM is] described as ‘polio-like’ because it sort of acts a lot like polio in the way that we believe it’s a viral infection of the motor nerves in the spinal cord,” she said. “And, really, polio is the classic thing that does that or did that.”

### **How common is AMF?**

“In a general sense, it’s very rare,” she said. “However this year, two years ago, four years ago — so 2014 and 2016 — we definitely saw, along with the rest of the country, clusters of cases where we had multiple patients in the span of a couple of

months. And it didn't feel rare during those clusters on a neurology ward, but in between those clusters, we really don't see this condition often at all."

The season for the illness, when it occurs, appears to be August, September, and October, Benson said.

### **What are the symptoms to watch for?**

Benson said she's hopeful there won't be a lot more cases in Massachusetts since the season is likely coming to a close.

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"The symptoms most often are weakness of an extremity starting in one and sometimes spreading to other extremities," she said. "And sometimes it's a shoulder or a hip that are the first sign of weakness. It can also be pain associated in the back or in the limb that's affected. Those are the biggest, first signs that there's something going on."

In addition to the sudden onset of muscle weakness, the state public health department said slurred speech, difficulty swallowing, and difficulty moving the eyes can also be experienced by patients.

"It's a scary thing, and it's hard not to be fearful for your own child, but it's also an extremely rare thing," Benson said. "The only thing within people's control is good infection control."

That includes coughing into your elbow, washing your hands, and taking the precautions you would normally take to avoid the common cold.

"So other than kind of general precautions, there's not a lot to do," she said. "But certainly if someone has been sick and starts to notice their child isn't walking or moving correctly, you should get that checked out as soon as possible."



**EXHIBIT NO.**

**15**

# **They cry in their hospital beds: Mothers of two boys diagnosed with mysterious polio-like illness reveal their sons' heartbreaking struggle to breathe, move, and come to terms with their paralysis**

- Sebastian Bottomley, seven, of York, Pennsylvania came down with a common cold two years ago
- Within days he was left paralyzed and doctors diagnosed him with acute flaccid myelitis (AFM)
- He is in a wheelchair despite 2,000 hours of physical and occupational therapy
- Camdyn Carr, four, of Roanoke, Virginia, was diagnosed with AFM after he came down with a cold in August
- He can only wiggle his fingers and toes and move one leg and he is unable to breathe on his own
- This year, 72 children in 22 states diagnosed with AFM, with another 83 under investigation

By MARY KEKATOS HEALTH REPORTER FOR DAILYMMAIL.COM  
UPDATED: 11:25 EDT, 1 November 2018

A mother has revealed her child's heartbreaking words after contracting a rare polio-like illness that may leave him paralyzed forever.

Two years ago, Sebastian Bottomley, seven, came down with a common cold. But soon he developed muscle weakness, and eventually was left completely paralyzed.

After running numerous tests, doctors in York, Pennsylvania, diagnosed him with acute flaccid myelitis (AFM), an infection that causes sudden paralysis.

# Daily Mail

This year, at least 72 children in 22 states have been diagnosed with AFM and another 83 are being investigated.

Despite undergoing more than 2,000 hours of physical and occupational therapy, Sebastian remains stuck in a wheelchair and unable to walk - a situation that has frustrated and exhausted him.

'Occasionally he says things like: "Mom, why can't I just walk like everybody else does without all this work?",' his mother, Christa, told [CBS News](#).





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Two years ago, Sebastian Bottomley, seven (pictured), of York, Pennsylvania, also had symptoms resembling a cold and was diagnosed with AFM



© Chris Carr via ABC 11 News

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**Camdyn Carr, four (pictured), of Roanoke, Virginia, came down with a cold in August. Within two weeks, he was paralyzed and was diagnosed with acute flaccid myelitis (AFM)**

Her words come as another mother of a child diagnosed with AFM reveals that his ordeal with the condition has left him crying in his hospital bed.

Soon after Sebastian began sniffing in August 2016, he started displaying muscle weakness. Then, he couldn't move any body part below his neck.

After a battery of tests, doctors finally diagnosed him with AFM.

AFM is a rare, but serious condition that affects the nervous system. Specifically it attacks the area of the spinal cord called gray matter, which causes the body's muscles and reflexes to weaken.

Symptoms often develop after a viral infection, such as enterovirus or West Nile virus, but often no clear cause is found.



Patients start off having flu-like symptoms including sneezing and coughing. This slowly turns into muscle weakness, difficulty moving the eyes and then polio-like symptoms including facial drooping and difficulty swallowing.

In rare cases, AFM can cause neurological complications that could lead to death.

Sebastian has had to undergo numerous surgeries and he's been hospitalized more than 200 times in the last two years.

However, after 2,000 hours of physical and occupational therapy, Sebastian is finally able to dress himself, feed himself, stand up and use the restroom

'I can walk, I can move my arm and I can like, kneel, and I can scooch on the floor up and down stairs,' Sebastian told WJZ13.



© Christa Bottomley/Facebook

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Sebastian has undergone three surgeries and 2,000 hours of physical and occupational therapy. Pictured: Sebastian relearning how to walk



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**He is finally able to dress himself, feed himself, stand up and use the restroom. However, he has been left confined to a wheelchair (left and right) since his diagnosis**

After 2,000 hours of physical and occupational therapy, Sebastian is finally able to dress himself, feed himself, stand up and use the restroom

'He's been hospitalized almost 200 days in the past two and a half years,' Christa told the newspaper.

However, he still gets around in a wheelchair and relearning to walk has been a difficult journey.

Camdyn Carr, four, of Roanoke, Virginia, has also been left frustrated by his slow progress that often leaves him crying in his hospital bed.

For Camdyn, it started out as a common sinus infection. However, just two weeks later, the entire right side of his body was paralyzed.



Just 24 hours after that, he was completely unable to move or speak.

Doctors at the University of Virginia Health System told Camdyn's parents, Chris Carr and Brittany Hoff, that he had AFM.

'There's no answers for why he got it,' Hoff told WSET. 'The doctors said there's nothing that we could have prevented, there's nothing that we could have done.'



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Camdyn (before AFM, left, and after AFM, right) is unable to breathe on his own and has had a trach inserted. He is undergoing intense therapy but is unable to speak and is only able to wiggle his fingers and toes, and move only one leg

<https://www.dailymail.co.uk/health/article-6339055/Two-boys-4-7-mysterious-polio-like-illness-reveal-devastating-impact-virus-left.html>



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**At least 72 children in 22 states have been diagnosed with AFM and another 83 are being investigated. Pictured: Camdyn in the hospital**

No specific treatment is available for AFM and interventions are generally recommended on a case-by-case basis.

Children with weakness in their arms or legs may attend physical or occupational therapy.

However, physicians admit they are unaware of the long-term outcomes for those with AFM.

Currently, Camdyn is at the Kennedy Krieger Institute in Baltimore, Maryland, where he is undergoing intense physical therapy and he is expected to remain there until December 18.

'[Doctors] said that he will never recover. For the rest of his life - paralyzed,' said Hoff.

Currently, he is unable to speak and is only able to wiggle his fingers and toes, and move only one leg.

'He seems okay sometimes, but there are a lot of times where he's crying,' Chris Carr told WSET. 'And I know it's because he can't speak.'

A **GoFundMe** page has been set by Camdyn's family to help cover expenses once he goes home. So far, more than \$3,200 of an initial \$3,000 goal.